

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
1 March 2001 (01.03.2001)

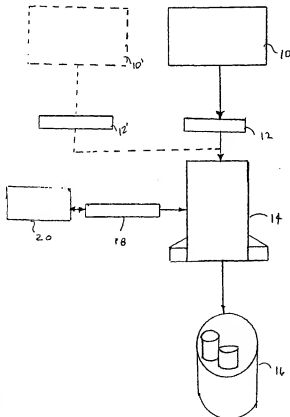
PCT

(10) International Publication Number  
**WO 01/15043 A1**

- (51) International Patent Classification<sup>7</sup>: G06F 17/60, G09B 23/28
- (21) International Application Number: PCT/US00/22848
- (22) International Filing Date: 20 August 2000 (20.08.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/150,062 20 August 1999 (20.08.1999) US  
60/150,110 20 August 1999 (20.08.1999) US
- (71) Applicant: ST. CROIX MEDICAL, INC. [US/US]; Suite 113, 5301 East River Road, Minneapolis, MN 55421 (US).
- (72) Inventor: HOAG, Douglas [US/US]; Suite 113, 5301 East River Road, Minneapolis, MN 55421 (US).
- (74) Agents: KEOUGH, Steven, J. et al.; 900 Second Avenue South, 1000 International Center, Minneapolis, MN 55402 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— With international search report.

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR ONLINE MEDICAL DATA MANAGEMENT AND TRAINING



(57) Abstract: A comprehensive intranet/extranet site (40) implemented in a computer system (14) to enable users to access distinctive and functionally interactive sub-sites (29) or rooms to learn about a medical device system (46), manufacturer's data and information (48), understand hearing loss (50), provide physician education and training on surgical procedures, paramedic support, sales education and training, provide patient education and verification (52) and provide a library (54). The invention further relates to a real-time processing of medical forms. The invention also includes a scheme in which a physician is enabled to adjust and fine tune, locally, an implanted hearing aid using a physician programmer (147) and a radio frequency telemetry device (152); and to prospectively enable a remote adjustment based on interaction between the physician programmer (147) and a patient programmer (155) being communicable via the intranet (40).

WO 01/15043 A1



- 
- *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## SYSTEM AND METHOD FOR ONLINE MEDICAL DATA MANAGEMENT AND TRAINING

### BACKGROUND OF THE INVENTION

#### Field of the Invention

The invention relates to a computer-implemented intranet/extranet demonstrable and accessible system for remotely managing and training product support and sales personnel, surgeons, clinical trial data managers, patients, and patient families.

#### Description of Related Art

The Internet comprises a large number of interconnected network of computers. The environment of network computers forms the basis of the Internet and involves in the sharing of information and messages on the Internet. These information and messages are structured into packets for transmission. When the packets reach their destination., they are reassembled into their original format such that the receiving computer in the network may be able to read or view them. Transmission Control Protocol (TCP) and Internal Protocol (IP) systems are used to effect this transmission and conversion of information and messages.

Generally, the TCP breaks down the packets and reassembles them at the point of delivery/reception. On the other hand, the IP ensures that the packets are sent to the right destination. The Internet normally utilizes a packet-switched network and therefore there is no single unbroken connection between sender and receiver. Thus, when information is sent, it is broken into small packets, sent over many different routes at the same time and then reassembled at the allocated receiving point.

The backbone of the Internet was originally a series of high-speed links between major supercomputer sites and educational and research institutions within the U.S. and throughout the world. Currently large commercial Internet Service Providers (ISPs) provide links to subscribers. As discussed hereinabove, Internet computers use TCP/IP communications protocol. There are several million hosts on the Internet. A host may be a mainframe, mini, work station or high-end PC that is on line via TCP/IP. Further, the Internet is also connected to several types of computer networks worldwide through gateways that convert TCP/IP into other protocols.

In accordance with the present invention an in-house web site that serves the employees (and other privileged users with access) of a company is called an intranet.

Although intranet pages may link to the Internet, the general public may be restricted from unauthorized access. Using programming language such as Java, or others, client/server applications can be built on intranets.

Further, since web browsers that support Java run under Windows, Mac and Unix, such programs also provide cross-platform capability. Intranets use the same communications protocols and hypertext links as the world wide web and thus provide a standard way of disseminating information internally and extending the application worldwide at the same time.

A typical single web network consists of at least four parts. These four parts include a client computer, a host server, an internet service provider (ISP) and a data/information transfer communication system between the three which is required to form a competent web connection. Host computers are ubiquitous throughout the Internet and house web pages. Additionally, host computers are designed to support multiple telecommunications between various client computers.

The Internet consists of many different types of files. Each file includes information contained in its header for both identification and location in the server. Generally, software systems that are compatible with a file can read the file and check the header to identify the specific file and execute a command or process thereon.

Further, the Internet normally works on a server-client system of information delivery. Thus a client computer is connected to a server which contains the necessary data/information the client would need to access and use. The client is served by the larger computer or server. For example, a service may include searching for information and sending it to the client. Specifically, the client is a local personal computer and the server is usually a more powerful computer in which the data is stored. Servers may be Windows-based PCs, Macintoshes and a number of other types of hardware that run the UNIX operating system. The connection to a server may be made by a phone line or modem, LAN (local area network) or TCP/IP based WAN (wide area network). A network may be formed to enable a number of client computers to access the data stored in the server. In the case of the World Wide Web, the client is the browser which is implemented in the user's computer and the host is virtually any server that is being accessed on the Internet. Typically, the browser requests for a web page on a server and generally the server responds to the browser by either confirming/opening the web page or rejecting the request.

Businesses increasingly use Internet technology. Specifically, intranets are being used in corporations and other businesses for e-mail, computation, group access to a data

base, video conferencing and other similar activities. As discussed hereinabove, intranets implement TCP/IP networks in addition to Internet resources. The intranet is segregated from the Internet by using a security system such as a firewall or equivalent. Generally the security system comprises a hardware and software system which prevents unauthorized access to the intranet. Intranets use software which is readily available in the market. However, most intranets implement custom made software to execute specialized operations. Intranets are most conducive to work group applications.

Although there is a strong and emerging trend in providing highly integrated and robust intranets, existing systems lack the structure and architecture to be readily adaptable for use by clients, internal personnel and a variety of user groups who are vital to the service and operations of a corporation or business. A case in point is the operations of the assignee of record of the present invention. The assignee's business requires interaction between patients, medical doctors, research and marketing personnel, and a number of other functional units. For example, there is no computer based training for assignee's hearing aid devices. Further, there is a need for a quick and accurate interaction between an ear implant patient, a doctor, administrators and other functional units in the chain. This extends also to pre-clinical and clinical trials worldwide.

Accordingly, there is a need to develop a work group software to enable the assignee of record to more easily share files and information across its widely distributed operations. Further, there is a need to educate a variety of audiences on a complex, highly technical product. The implementation of a specialized intranet system and particularly the use of a customized work group software to allow for all data and information to be stored on a preferably single source eliminates duplicating and adjusting marketing materials, for example, to each specific audience. Further, tutorial sessions with tracking features may be implemented to allow for accurate monitoring of user understanding.

Thus, pursuant to assignee's business objectives, there is a need for an intranet system and work group software to bring all physicians to the same level of understanding of relevant products prior to participation in the live training for the products. Further, there is a need to educate patients (and their families) and address their concerns about products and surgery so that they are better informed. There is a further need to educate a segment of the public on hearing loss and about available state of the art remedial medical procedures and products. There is also a need to prepare medical personnel to serve and support patients.

Otology therapy and treatment has continually advanced over the years. Although there have been significant historical dates in otology therapy, the modern trend of using

hearing aids was ushered in after the invention of the transistor. In December 1947, Bell Laboratories invented the transistor and changed the size of the hearing aid forever. Hearing aids powered by transistor batteries appeared in late 1952. The reduced size of the battery permitted hearing aids to be worn behind-the-ear and on eyeglasses. Further, advances in surgery such as Stapedectomy and Tympanoplasty augmented electronic hearing aid devices of the late fifties and early sixties.

Hybrid hearing aids were introduced in 1977. These types of hearing aids use a combined analog and digital circuitry. One of the important advances of hybrid hearing aids is increased flexibility when fitting the hearing impaired person. Like transistor hearing aids these can be worn in-the-ear, behind-the-ear and in-the-canal.

Technology in hearing aid devices has closely tracked the evolution of advanced micro-electronic systems. In this regard the emergence of digital and programmable hearing aids utilize digital signal processing, a technology that matured for broad practical applications in 1982. The first commercially produced wearable digital signal processing hearing aid was manufactured in the late 1980s. Because it was cumbersome and expensive it was not a commercial success. Programmable hearing aids provide a small chip that is programmable to be tailored to an individual's needs. These units offer high fidelity and lower distortion levels than traditional hearing aids. These units are implemented behind-the-ear and in-the-ear.

The assignee of the present invention has developed an advanced implantable hearing aid, known in one embodiment as the Envoy™ hearing aid. However, the origin of implantable hearing devices must be viewed in light of the history of hearing devices in general. Three general classes of product features can be identified as emerging trends in the process of innovation of all types of hearing aid devices and instruments including the implantable type: (1) miniaturization, (2) sound enhancement and fidelity, and (3) related convenience features.

#### SUMMARY OF THE INVENTION

It is the object of the present invention to provide a computer-implemented interactive system. Generally the system includes a physician education and training, paramedical support, sales education and training, and patient education and verification sites in an intranet accessible by a user via a terminal. Specifically the system includes means for

identifying and granting access to the user; means for displaying a plurality of interactive sites; and means for selecting among one of the sites.

The present invention also generally relates to an interactive information and instruction system. The system is preferably based on an intranet and extranet sites using special protocols including transmission control protocol (TCP) and the Internet protocol (IP). Specifically, the invention relates to a highly functional, modularly structured extranet site to enable direct submission of data for surgical procedure applicants, product support, training and customer/user information center. More specifically, the intranet site is menu driven and is advantageously implemented for use by a diverse group of audiences including physicians, audiologists and technicians, hospital/clinic administration, paramedical support personnel and lead investigators.

The present invention also relates to a computer-implemented patient-interactive software tools. Specifically, the invention relates to a functional, preferably, intranet-based system which enables a user to navigate a number of sites to provide education on hearing impairment conditions, hearing aid devices and further includes a self-directed evaluation and assessment of the user's sound perceptions.

Yet another object of the invention is to provide an interactive training system in which a hand holdable telemetry wand is used to program a hearing aid device and is accessible for training purposes via interactive screens. This aspect of the invention includes a physician programmer; a patient programmer; and a telemetry wand. The physician and patient programmers include the telemetry wand having independent interactive screens.

A further object of the invention is to provide an interactive education and training intranet site in which patients, physicians, paramedics and sales personnel are trained by navigating the sites to explore the various functions of a remedial implantable hearing aid and the human auditory system. Specifically the intranet site includes, in relevant parts, a physician site; a patient site; a paramedic site and a sales/marketing site.

The present invention provides hitherto unavailable seamless product and operations support at various levels of a business. Specifically, the invention relates to a computer system, preferably an intranet and extranet network in which patients, physicians, clinic administrators, researchers, product sales and marketing personnel and all other necessary operations are integrated to advantageously provide a synergistic product information and support for a hearing aid device.

It is one of the objects of the present invention to provide a computer system to enable users to access a client server and database to submit application forms under a secure protocol via a customized user interface within an intranet. Specifically the invention enables the submittal and approval, in real time, of forms submitted by a clinic, for example.

It is yet another object of the invention to provide a functional intranet site implemented in a computer system for interactively processing application forms, product support matters including instructions and training.

It is a further object of the invention to provide a method for processing data in a computer network system having a secure host and a database for storing objects in the main server wherein the main server is accessible in a web under an extranet via a modem. The method includes a process for managing the submittal and approval of a form, in real time, through various disparate administrative and authority channels. Further the method includes the use of the computer network to support intranet and extranet sites for tutorials, training and general information about assignee's products and services.

It is yet a further object of the invention to provide an advanced, preferably microprocessor based, device for use to noninvasively analyze and change settings in a hearing device. Using radio frequency telemetry or equivalent, a wand relays information to and from the implanted hearing device.

With these and other objects, advantages and features of the present invention that may become apparent, the nature of the present invention may be more clearly understood by reference to the following detailed description of the present invention, the appended claims and to the several drawings herein contained.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a representation of the overall process of the present invention depicting electronic and data communications between servers, database storage and various computing stations;

Figure 2 is a representation of a screen to log on the intranet with instruction therefor;

Figure 3 is a representation of a screen with buttons to provide a user a selection of options on where to go in a main lobby;

Figure 4 is a representation of a screen with buttons to provide a user a selection of options on where to go in The Envoy System room;



Figure 5 is a representation of a screen with buttons to provide a user a selection of options on where to go in The St. Croix Medical room;

Figure 6 is a representation of a screen with buttons to provide a user a selection of options on where to go in The Understanding Hearing Loss room;

Figure 7 is a representation of a screen with buttons to provide a user a selection of options on where to go in The Education and Training room;

Figure 8 is a representation of a screen with buttons to provide a user a selection of options on where to go in The Library room;

Figure 9 is a screen display example in The Surgery room for interactive training;

Figure 10 is a schematic representation of a screen display of the invention relating to a programming system for a hearing assistance device such as the Envoy<sup>TM</sup> system;

Figure 11 is a representation of an inner portion of the ear activated from the screen of Figures 12 or 13;

Figure 12 is a representation of portions of the ear wherein each of the pictures are provided with buttons for zoom, return to main lobby (home) and other links;

Figure 13 is a sectional view of the major parts of a human ear including the outer, middle and inner ears with specific activatable access to a detailed library of information on each of the parts displayed therein;

Figure 14 is a representation of an audiogram-related screen for use in a self-directed hearing assessment and patient hearing profile analysis and depiction;

Figure 15 is a representation of an audiogram-related screen for use in a self-directed hearing assessment and patient hearing profile analysis and depiction;

Figure 16 is a representation of an audiogram-related screen for use in a self-directed hearing assessment and patient hearing profile analysis and depiction;

Figure 17 is a representation of an audiogram-related screen for use in a self-directed hearing assessment and patient hearing profile analysis and depiction;

Figure 18 is a screen display useful in training sales and other personnel in comparison to competitive concepts.

#### DETAILED DESCRIPTION OF THE INVENTION

The present invention is a computer-based data system which utilizes a log-on code to allow a user to access features that pertain to a functional group of interest. Specifically, the invention is implemented to serve sales and marketing, physicians, paramedical support technicians, plastic surgeons, patients, and other selected users. The system comprises an

intranet site which includes a detailed and accurate multi-dimensional medical illustration, detailed and multi-dimensional medical animations, a three dimensional virtual model and environment, video movies in a window, audio including narration, music interludes, sound effects, and innovative teaching tools.

Primarily the invention includes a plurality of related functional elements which are intranet/extranet implemented. The first part of the invention enables real-time submittal and approval of medical forms while the second part relates to a modularly structured information, instruction and sales training sites. Specifically, the second part includes at least four rooms or sub-sites which contain information and interactive video of product-related technology, information about the sponsor corporation, information about hearing loss, education, testing and a medical-scientific library.

Referring now to Figure 1, a general overview of the process steps and the major hardware involved is represented. Specifically, and by way of example only, a personal computer or functionally equivalent component 10 at a clinic is connected to the sponsor Extranet site from a CD-ROM, or equivalent medium, or by direct access to the site. As is often the case, the user will be required to enter the appropriate URL, a password and user ID. Modem 12 is implemented to access the host (sponsor) server 14. Upon verification from server 14, access to an electronic form is granted and the clinic or user fills out the form while on the site. Thereafter, the form is submitted to server 14 and database storage 16. The form is again checked for accuracy to see if all the necessary data has been entered. If not, the form is rejected and feedback is given immediately to the user indicating the actual missing data. Component 10 at the clinic will then modify the form and resubmit it. When a successful form is confirmed, and is accepted by server 14, the data will be submitted to database storage 16. The form will then be permanently stored as a read only file to prevent any changes, unauthorized access, or tampering with it. Additional data may be attached to the approved form but any changes/modifications will not be allowed, outside of the verified process. After an application form is successfully submitted and stored in database storage 16, it is placed in a pending file. Thereafter an e-mail message is sent via modem 18 to a lead investigator at component 20. The lead investigator must log online to view the submitted form and to verify its accuracy. As indicated hereinabove, the form will be in a read only and therefore the lead investigator can only approve or disapprove but cannot make any changes to the form. If the form is not approved by the lead investigator, it is placed or archived in an unapproved file and may be deleted later. In the alternate if the form is approved by the lead investigator, it is routed to the appropriate contact at the sponsor's site for further

approvals and processing as needed. The form then is moved from the "pending" to the "approved" file within database storage 16. As will be shown later as well, this system and method affords great benefit to remote or distributed medical trials, and the management of data obtained at multiple or remote sites in a timely and validated manner.

Referring now to Figure 2, a representative logon screen 22 to access the extranet server 14 is shown. The log on menu requires the entry of a user name and associated ID. The user then clicks on Login key and the connection is made. It is appreciated that various user or guest options are possible to facilitate ease or difficulty of access to various portions of the Extranet, as is contemplated in the art.

Applicants have realized that as medicine and medical device systems and methods has evolved, the extent of patient involvement has increased, often depending on the condition being diagnosed or treated. Indeed, an emerging trend of greater patient and patient's relatives being integrated into treatment options is recognized and promoted in an innovative manner using various components of this invention. The first example of this is the desire of applicants to create a manner and atmosphere (to the viewer/user) of a comfortable medical office, and the sense of assurance in obtaining the most accurate and understandable answers to the questions and concerns of the patient and his/her family or caregivers. Indeed, the atmosphere projected by this invention may even exceed that level of support normally found in some medical practitioners' office environs. Figure 3 is a screen display 26 of The Main Lobby portal for the user. At this screen, activated option buttons, which illuminate when scrolled over, provide a menu of options for the user. These buttons 29 are conveniently arranged at first portion 33 of the screen, with corresponding doors 37 which also activate when scrolled over or clicked on at a second portion 40 of the screen.

While it is recognized that the system and method of this invention is appropriate for a variety of medical devices and related products and services, such as for example that class of implantable medical device known generally as "Class I" and including products such as defibrillators, pacers, pain management components, and others, the primary example which is used herein is of the Envoy brand implantable device for hearing assistance. This is used to exemplify and simplify the examples, rather than to necessarily limit the application of this invention and its many embodiments.

Buttons 29 of Figure 3 illustrate exemplary categories to guide the user, including The Main Lobby 44, The Envoy (or other product name) System 46, St. Croix Medical 48 (or other sponsor name), Understanding Hearing Loss 50 (or some other condition), Education

and Training 52, Library 54, Exit 56. The Main Lobby room allows the user to select the desired subsequent room or data area to enter. Selection of one of the buttons 29, or other equivalent feature, takes the user to various other screens. For example, screen 65, shown in Figure 4 illustrates the The Envoy System room and is designed to provide the physician, audiologist, and patient with information about the Envoy system functions, including details of the various components within the Envoy system and technology behind each component. The St. Croix Medical room, shown as screen 70 in Figure 5, is designed to introduce the user to the background and expertise of the company that produces the (Envoy) product. The Understanding Hearing Loss room, shown as screen 75 in Figure 6, is designed for anyone who has a need for consultation, such as a patient or the patient's family. This room allows access to information relating to a medical condition or indication, such as in this instance hearing loss, hearing testing, or frequently asked questions. The Education and Training room, shown as screen 80 in Figure 7, is designed for providing information and interactive training to surgeons and other physicians, as well as patients. Further discussion of this room is contained hereinbelow. The Library room, shown as screen 85 in Figure 8, provides resources and background information on the medical condition and a variety of related topics.

It is understood that various arrangements of screen display may be employed within the scope of the invention. One layout of an example of a body text and picture arrangement may be 570 pixels wide and 430 pixels high. A navigation strip/area may also be allocated having 50 pixels height. Other sizing may be utilized.

Referring again to the Education and Training room, screen 80 of Figure 7, there is shown the buttons labeled The Surgery 100, The Programmer 104, and Consent Form 108. Selection of button 100 (The Surgery) allows the user to learn more about the surgical or other procedure contemplated. This room may be a restricted room to which only physicians may have access, according to the desires and permissive links installed by the sponsor of the invention in use. Figure 9 illustrates one example of how the invention allows the surgeon to train for the surgical procedure using patient model 121, having surgical area 125 outlined with demarcation 128. Pop-up and movable surgical instrument tray 133 provides the appropriate surgical instruments 136 for use during the procedure. The user (medical provider) is able to select the desired instrument combinations and manipulate the instruments for use on the model 121. Interactive feedback is provided to the user if an undesirable instrument selection is made relative to a particular step in the surgery. Audible or visual alerting and recommendations follow such a selection to prompt the user to more

acceptable or standard techniques and instruments. In similar manner, the model may comprise an interactive model that alters views of the procedure as the surgery progresses. For example, the model may change from the skull view to a view within the skull as the surgeon moves the instruments through the outer bone and into the middle ear region. If, for example, the facial nerve was nicked then the alert would activate and the user may be prompted to remedial action. Thus, this invention selectively allows improved intranet-based training for physicians and caregivers.

Also, at Figure 7, election of button 104 labeled "The Programmer", results in the viewer entering a screen which facilitates either the medical caregiver or the patient in a greater understanding of a component of the implanted or other medical device or product. Figure 10 illustrates representative screen 144 which relates to physician programmer 147. The physician programmer 147 is an advanced microprocessor-based device which is used to non-invasively analyze and change settings in the product, for example the Envoy<sup>TM</sup> Electronic Piezokinetic Ossicular Replacement Prosthesis (E-PORP) System. Programmer 147 communicates with the implanted Envoy E-PORP using handheld telemetry wand 152 or other means of data transfer.

The Envoy<sup>TM</sup> device senses sound waves from the malleus bone, converts the sound to an electrical signal, amplifies and filters the sound, and transmits the signal to the stapes where the signal then is transmitted to the cochlea. The amplification and filtering are matched to the individual patient's hearing requirements using one of two external programming devices, namely: representative physician programmer 147 or representative personal programmer 155.

Before a patient is discharged from the hospital or clinic, physician programmer 147 sets the initial parameter limits in the implanted device (Envoy E-PORP), based on the patient's baseline thresholds and indications. The physician programmer 147 also performs diagnostics by transmitting tones to the implanted device. The physician may then utilize various forms online within this system and related databases, such as setting or confirming sound processor parameters, assessing and documenting patient specific history or other data, recording and reporting audiograms, scores, and other reflex data, wand tester data, etc.

Telemetry wand 152 may also include a cable which plugs into the serial port on the physician programmer 147. Using non-invasive inductive coupling, telemetry wand 132 establishes communication with the implant. Specifically communication is established by placing wand 152 over the implanted electronics module, whether it is located at the head,

upper torso area or lower torso area of the patient, any of which is possible. Wand 152 relays information from and to the Envoy<sup>TM</sup> system using radio frequency telemetry.

Information and data on the intranet regarding physician programmer 147, wand 152 and personal programmer 155 is given with buttons to open text and instructions relating to physician programmer 147 and wand 152. Further, the intranet provides timely instructions on how to use both physician programmer 147 and personal/patient programmer 155. The patient for example may compare prior settings with current ones and learn proper and correct methods of making adjustments as needed.

In the embodiment shown in Figure 7, screen 80 also includes button 108, which accesses a Consent Form as appropriate for obtaining patient consent to the relevant medical procedure. the online management of the form contents, combined with possible online consent legal possibilities according to venue, affords further advantage to this invention. Patient education and reduction of fear or apprehension is also improved by use of this button. The availability of the consent form for prior review and discussion is quite useful.

The invention further comprises means for enhanced patient and family education and preparation for the medical procedure through accessing the How You Hear button 173 in the Understanding Hearing Loss menu selection, as shown in Figure 6. Screen 177 of Figure 11 represents a magnified view of the cochlea and semicircular canals. The view is accessed by clicking on a magnification box 192 for the inner ear on screen display 195 in Figure 12. The buttons operate and function principally under the following conditions: Clicking a "Done" button puts box away and returns the user to a dedicated screen with zoom boxes. Clicking a "zoom" button brings up box of magnifiable area and clicking a "Reveal" button brings user to the screen.

Rolling over various highlighted areas brings up further temporary labels of the area being scrolled, such as the labels shown on screen 201 in Figure 13, e.g. bony labyrinth, vestibule, oval window, round window, semicircular canals and cochlea, etc. Each of these elements may further be defined, as needed. For example, clicking on each of the labels of the highlighted area brings up the following example text:

The vestibule constitutes the central section of the bony labyrinth. Into it open both the oval and round windows from the middle ear as well as the three semicircular canals of the internal ear. Inside the bony labyrinth is the membranous labyrinth.

The cochlea, which begins at the oval window, is a fluid-filled spiral shaped tube that resembles a snail shell. The cochlea is really the organ of hearing, since it is here that waves in the fluid, which fills the cochlea, are detected by tiny hair cells. The bony labyrinth may be viewed by clicking on the boxed area for a magnified view of that structure.

It is again emphasized that the example of hearing loss and ear anatomy is but one of various conditions and anatomic regions which this invention may apply to, without undue limitation. As shown above a preferred mode of enhancement is to have the graphics accessed by clicking on the zoom button. Specifically, the zoom button brings up boxes around the magnifiable areas and changes screen instructions, however, alternate schemes may be utilized for magnification. According to the present invention, virtually any magnified view may lead to a sublayer of elements to be viewed.

Another form of patient education tool within this invention is accessed by selection of the Understanding Hearing Loss button 50, shown in Figure 3. In addition to an educational and fascinating timeline of hearing technology evolution, accessed at button 206, labeled History, screen 75 of Figure 6 allows access to a screen labeled How You Hear. Accessing this screen reveals options that comprise sub-screens Audiogram and Types of Hearing Loss, among others. Selection of Audiogram reveals screen 222 shown in Figure 14, which illustrates the hearing level in decibels of a patient's right ear (x) and a left ear (o) versus frequency in cycles per second. In this example, there is progressive hearing loss in the higher frequency ranges, a condition common to millions of people. However, an important aspect of the advantage of this screen is the button 226 labeled "Example", which, when selected, produces the image of screen 235 shown in Figure 15. On this screen, the audiogram is littered with smaller activatable buttons or other icons 241, which represent the mean sound level and frequency of the well known events depicted, such as a large barking dog, a jet aircraft, a crying baby, a chirping bird, a truck, etc. This visualization of sound level and frequency has been found to be quite useful in educating patients and patient families. However, when this tool is further combined with the tools shown in Figure 16, then even further advantage is derived. Screen 271 of Figure 16 illustrates a plurality of different hearing loss scenarios which may be selected at buttons 278, in this embodiment, pre-selected to demonstrate what a patient hears who is suffering from hearing degradation at a mild level, and at more severe levels down to a 2000 Hz level, a 1000 Hz level, a 500 Hz level, and a 250 Hz level. As each level is selected by button activation, an audio voice of a

reader is activated. As the voice reads, the spectrum display 286 tracks a cursor 288 across the display corresponding to the voice, and the hearing level is plotted on the audiogram 291. Figure 16 shows a normal hearing level, while Figure 17 shows a 500 Hz level of hearing on audiogram 291 and spectrum display 286. In the example of Figure 17, the speaker's voice is barely audible as a non-discernible muffled noise. The combined aural and visual impact of these above described screens is a unique and powerful educational tool for patients, families, and even healthcare providers.

Accordingly, the present invention provides several interactive screens and text to educate, inform and clearly describe the elements of the human ear and the many specialized functions of the organs involved therein. The computer system utilizes an intranet site which is accessible from an extranet and is functionally operable to access instructional/informational data about the human ear.

Screen 302 in Figure 18 represents a customer service/marketing training section of the intranet for the present invention. Addressing customer complaints and objections in a timely and fair manner is a critical part of doing business. The intranet of the present invention includes a site for exercises and for training sales and marketing personnel on the hearing aid device, or other featured medical device, e.g. a class one implantable medical device. The exercises pose realistic scenarios in which pre-sale/post-sale interviews with a client are simulated. The exercises are programmed to sharpen the competitive edge by including a competitive segment in which the user is required to compete with another imaginary representative of the product corporation in another territory. An award bonus is posted to reward the party with the most points.

The user is prompted to select a case by clicking on a tab. For example, a screen relates to an overview of a role-play exercise. Clicking on the designated room for Education and Training accesses the section. Case tabs enable the user to switch from one case to another, at any time.

Accordingly, the present invention provides a highly instructional and interactive intranet for product support, information and use. Specifically, the invention relates to a highly functional, modularly structured extranet site to enable direct submission of data for surgical procedure applicants, product support, training and customer/user information centers. More specifically, the intranet site is advantageously implemented for use by a diverse group of audiences including physicians, audiologists and technicians, hospital/clinic administration, paramedical support personnel and lead investigators.



The invention also comprises using intranet and internet sites to educate users and others about the human auditory system, hearing aid devices and implantable hearing aids. The invention implements search and query functions which enable users to navigate layered segments of bundled text, audio and video representations including related sites accessible via HTML linkups.

The present invention operates on the client/server model of information delivery. Under this model, a client computer connects to a server computer on which information resides. Thus, the client depends on the server to deliver information. Typically, in the present invention the client is an individual in need of access to the server directly or via the Internet. The computer can be of many different kinds of powerful Windows-based PCs, Macintoshes, and a wide variety of hardware that runs the UNIX or other operating system. Certainly other systems and applications might also function as well.

The invention also includes a series of frequently asked questions. A questionnaire is designed to provide a comprehensive and interactive screen to frequently asked questions. Menu buttons enable navigation to the various screens of the site in both a forward and backward option using "hot menus" the clicking on a question brings the user to a screen with that question and answer. Clicking on a forward arrow brings the user to the screen for the first menu item or question. Clicking the back arrow brings the user to the prior introductory part of the site. Thus, the user may click on any question set and immediately go to the screen relating to the selected question. In the alternate, the user may click a menu button to move forward or backward across the various screens, consecutively. Answers to a question may include HTML or similar linkups to other intranet and/or Internet sites.

The site may also include displays for alternative methods of treatment, such as for example, traditional hearing aids, programmable hearing aid, digital hearing aid and the contralateral routing of signal (CROS) hearing aid. Further the site includes discussion of prosthetic improvements to conductive hearing including bone anchored hearing aids, non-invasive digital bone anchored hearing aid, partially implantable ossicular chain coupled systems, partially implantable tympanic membrane coupled device, totally implantable ossicular chain-coupled systems, cochlear implants and surgical procedures such as tympanoplasty and stapedectomy surgery.

The present invention provides a global training and education medium through which users may learn about hearing loss and remedial hearing aid devices. In particular the present invention utilizes an intranet system, preferably made up of various sites and applications sitting on top of standard World Wide Web servers and architectures and existing

Web formats such as the hypertext markup language (HTML). On a basic level, the invention forms an extranet site to extend communication and collaboration between a dedicated server and outside groups and users.

Furthermore, the present invention provides Internet compatible intranet sites adapted to demonstrate and display complex subjects with multimedia in three dimensional graphics, video and preferably viewable through 360° field of view. Generally, the user has to click on a highlighted area for description in a moveable text box. The user may also click zoom to identify areas for magnification.

It is therefore the object of the present invention to provide a functional intranet system implemented in a computer to enable a user to access a selection of subsites through a terminal which is assigned an internet protocol (IP) address and provides interactive sites to the user. The system preferably includes a computer with a server and proprietary database with operable data and electronic connections to the terminal. The system further includes means for accessing the selection of subsites. In the present invention rolling the mouse or equivalent over a designated area, for example, brings up a number of sites. A selection of one of the sites starts a text descriptive of the sight followed by illustrative figures.

Audiovisual sites are also included to be selectable by the user. The system is customizable by the user to hear and compare various sound levels and learn about the human ear.

Yet another object of the invention is to provide audiovisual means which includes displays associated with pre-set audiogram levels indicative of hearing profiles. Several hearing profiles and decibel graduations are implemented and depicted for the user to experience a self-directed hearing assessment. For example in one of the sites, the user is enabled to explore various commonly encountered sounds as they are perceived by a person with normal hearing. Further, audio-video sites are implemented to enable users to assess their hearing capacity.

Another object of the invention includes audio-video sites with displays related to pre-set audiogram levels designed to show hearing loss for patients and their families. Specifically, the user is educated about hearing loss and the auditory-environment of the hearing impaired. This enables patients to assess the degradation and the level of their hearing. Further the site enables friends and relative to share and understand sound perceptions of the patient. This is particularly useful in understanding the hearing impairment of children who otherwise may not be able to clearly communicate their

problems and difficulties in perceiving sound. The navigable sites of the invention include interactive graphical interfaces layerably structured to display various auditory elements of the ear.

It is yet another object of the invention to provide a computer system for allowing a patient to access ear and acoustic information and related data using a customized interface in an intranet site. The general objective is to educate the user in hearing loss and hearing aid devices. One of the many focal objectives is to educate patients on the Envoy™ system. The site is designed to be compatible with other sites via HTML linkups and enables importation of text and video from related sites.

Another object of the invention includes the use of a dedicated host computer which handles multiple telecommunications connections at one time. The host or server computer, hereinafter referred to as the SCM server, includes a large capacity hard-disk storage, considerable random access memory (RAM) and a high speed processor. The SCM server may preferably be made up of several computers linked together with each handling incoming intranet and Internet web page requests. The SCM server runs special web server software that reads requests sent from the client computer. The host also retrieves and sends the appropriate information to the client. The SCM server may preferably include dedicated links to the Internet backbone, or may be connected to the backbone via a network of hosts.

Yet another object of the invention is the implementation of sound, visual image, animation and video files to educate patients and other users about hearing loss and hearing aid devices. The implementation further includes streaming audio and video files which can be viewed while the user is on line, connected to the Internet. Generally, the implementation enables displaying various interactive ear, acoustic screens and sublayers thereof. These various interactive ear and acoustic screens include anatomy and physiology of the ear, physiological acoustics, psychological acoustics and speech communication screens, text and displays. The anatomy and physiology of the ear include interactive screen displays of the outer, middle and inner ear. The physiological acoustics preferably includes interactive screen displays of the acoustic properties of the outer and middle ear including cochlear mechanics and acoustic properties. The psychological acoustics includes frequency analysis and pitch perception screens and interactive animation and video. Specifically, the speech communication screens provide interactive screens for acoustical analysis of speech.

Yet another object of the present invention includes a computer system for allowing a user to access current therapy in otology including information and related data using a

customized interface in an intranet site. The system enables means for displaying various interactive otology therapy screens and means for displaying sublayers of the otology therapy screens. The interactive otology therapy screens preferably include external ear, middle ear and inner ear displays. The system further includes an interactive resource data screen implemented for the user to navigate relative to a given otological therapy. A questionnaire screen is implemented to gather information relating to the user's hearing problems. Further, an interactive screen and information on a hearing aid product and its performance is implemented to instruct the user about the state of the art in otology therapy.

With these and other objects, advantages and features of the present invention that may become apparent, the nature of the present invention may be more clearly understood by reference to the following detailed description of the present invention, the appended claims and to the several drawings herein contained.

WHAT IS CLAIMED IS:

1. A computer system for allowing a user to access a client server and data base and submit applications and forms in real time, under a secure protocol, via a customized user interface within an intranet site, the system comprising:
  - means for accessing the extra net site by the user;
  - means for identifying and granting access to the user;
  - means for filling out the form while on extranet site;
  - means for submitting the form in real time;
  - means for verifying the accuracy of the form;
  - means for maintaining the form on a read only file format pursuant to the form being verified accurate;
  - means for communicating the acceptance of the form to an investigator in real time; and
  - means for routing the form to the client server for storage after review by the investigator.
2. The system of claim 1 wherein said secure protocol includes autobots implemented as e-mail responders to indicate temporal sequence of activities.
3. The system according to claim 1 wherein said means for accessing includes a CD-ROM integrated with the extranet site.
4. The system of claim 1 wherein the data base includes rejected, pending and approved application files.
5. A functional intranet site implemented in a computer system for interactively processing application forms, product support matters and customer/ user input wherein physicians, audiologists, technicians, hospital/clinic administrators, paramedical support personnel, investigators and similar users are enabled to access a client server via a customized user interface, the computer system comprising:
  - means for accessing the extranet site by the user;
  - means for identifying and granting access to the user;
  - means for entering data while on extranet site;
  - means for submitting the data in real time;

means for verifying the accuracy of the data and consistency with the forms;  
means for maintaining the forms on a read only file format pursuant to the form being verified accurate;  
means for communicating the acceptance of the forms to an investigator in real time; and  
means for routing the forms to the client server for storage after review by the investigator.

6. The system of claim 5 wherein said means for accessing includes a remote station wherein one of a CD-ROM and URL is implemented including a modem being in data communications with the client server.
7. The system of claim of claim 6 wherein said modem is connected to the client server via a web to the extranet.
8. The system of claim 5 wherein said means for verifying includes an autobot checker.
9. The system of claim 5 wherein said means for communicating includes an e-mail system triggered at the point of the completion of the acceptance of the form to alert the investigator in real time.
10. The system of claim 5 wherein said means for entering data includes the forms and a bulletin board for submitting suggestions and comments.
11. In a computer system having a host server wherein the server is communicable to an intranet and extranet in a computer and further that the server is accessible to a pass-word identifiable user on the web via a modem, the computer system comprising:
  - the server being in data communications with a plurality of user stations;
  - a data base contained in the server including pending and approved files; and
  - one of said user stations being allocated to an investigator wherein accepted data is routed in real time for approval.

12. A method for processing data in a computer system having a secure main server and a database for storing objects in the main server wherein the main server is accessible in a web under an extranet via a modem to an approved user, the method for filling out electronic forms and submitting data by the user comprising the computer-implemented steps of:

- initiating the system using one of CD-ROM and URL means;
- displaying a form for the user to fill out;
- checking the accuracy of the form to verify if all the appropriate data is filled out;
- rejecting the form until submittal of a correct form is verified and accepted;
- alerting an investigator, in real time, when a form is accepted;
- maintaining the accepted form on a read only file;
- acquiring an approval from the investigator;
- routing the approved form to another station, if needed, to acquire one of additional approval and processing; and
- achieving the form in one approved, unapproved and pending file in the main server.

13. The method according to claim 12 wherein said step of maintaining an accepted form on a read only file includes the further step of allowing additional data to be entered while keeping the accepted form in its original format.

14. The method according to claim 12 wherein said unapproved form is deleted.

15. An interactively programmable system in which a hand holdable telemetry component is used to program a class one medical device in cooperation with a program resident in an intranet site, the system comprising:

- a physician programmer;
- a patient programmer; and
- a telemetry component;
- said physician and patient programmer being in communication via said intranet and said telemetry component being interfaced/plugged to said physician programmer.

16. A computer-implemented interactive system including a physician education and training, paramedical support, sales education and training, and patient education and verification sites in an intranet accessible by a user via a terminal, the system comprising:
- means for identifying and granting access to the user;
  - means for displaying a plurality of interactive sites; and
  - means for selecting among one of the sites.
17. The system according to claim 16 wherein said means for displaying includes optional buttons and controls to navigate the sites.
18. The system according to claim 16 wherein said means for selecting among one of the sites includes a plurality of graphical user interfaces to layerably navigate parts of a human ear.
19. The system according to claim 16 wherein said site for physician education includes surgical procedure cosmesis hints and tips.
20. The system according to claim 19 wherein said site for physician education includes surgery simulation.
21. An interactive training system in which a hand holdable telemetry wand is used to program a medical device and is accessible for training purposes via interactive screens, the system comprising:
- a physician programmer;
  - a patient programmer; and
  - a telemetry wand;
- said physician and said patient programmer including said telemetry wand having independent interactive screens.
22. The system according to claim 21 wherein said physician programmer includes a laptop screen, a cable screen and a wand screen.



23. The system according to claim 21 wherein said patient programmer includes interactive screen displaying an integrated volume and environment in which a sound system is set to fit the environment.
24. The system according to claim 21 wherein said telemetry wand includes at least one interactive screen displaying a wand tester dialog box.
25. An interactive education and training intranet site in which patients, physicians, paramedics and sales personnel are trained by navigating the sites to explore the various functions of a remedial implantable hearing aid and the human auditory system, the intranet site comprising:
- a physician site;
  - a patient site;
  - a paramedic site; and
  - a sales/marketing site.
26. The intranet site of claim 25 wherein said patient site includes various interactive sites to train the patient to understand hearing loss and use of hearing aid devices.
27. The intranet site of claim 25 wherein said physician site includes various interactive tools to train a physician to perform a successful surgery.
28. The intranet site of claim 25 wherein said paramedic site includes various interactive tools to train paramedics on patient follow up and hearing aid maintenance.
29. The intranet site of claim 25 wherein said sales/marketing site includes various interactive screens to train sales personnel in interacting with medical doctors.
30. The intranet site of claim 29 wherein said various screens provide interactive life-like interviews and sessions to enhance marketing personnel effectiveness.
31. A computer-implemented interactive system including a physician education and training, paramedical support, sales education and training, and patient education and verification sites in an intranet accessible by a user via a terminal, the system comprising:

means for identifying and granting access to the user;  
means for displaying a plurality of interactive sites, and  
means for selecting among one of the sites.

32. The system according to claim 31 wherein said means for displaying includes optional buttons and controls to navigate the sites.

33. The system according to claim 31 wherein said means for selecting among one of the sites includes a plurality of graphical user interfaces to layerably navigate parts of a human ear.

34. The system according to claim 31 wherein said site for physician education includes surgical procedure cosmesis hints and tips.

35. The system according to claim 34, wherein said site for physician education includes surgery simulation.

36. An interactive training system in which a hand holdable telemetry wand is used to program a hearing aid device and is accessible for training purposes via interactive screens the system comprising:

a physician programmer;

a patient programmer; and

a telemetry wand;

said physician and said patient programmer including said telemetry wand having independent interactive screens.

37. The system according to claim 36 wherein said physician programmer includes a laptop screen, a cable screen and a wand screen.

38. The system according to claim 36 wherein said patient programmer includes interactive screen displaying an integrated volume and environment in which a sound system is set to fit the environment.

39. The system according to claim 36 wherein said telemetry wand includes at least one interactive screen displaying a wand tester dialog box.
40. An interactive education and training intranet site in which patients, physicians, paramedics and sales personnel are trained by navigating the sites to explore the various function of a remedial implantable hearing aid and the human auditory system, the intranet site comprising:
- a physician site;
  - a patient site;
  - a paramedic site; and
  - a sales/marketing site.
41. The intranet site of claim 40 wherein said patient site includes various interactive sites to train the patient to understand hearing loss and use of hearing aid devices.
42. The intranet site of claim 40 wherein said physician site includes various interactive tools to train a physician to perform a successful surgery.
43. The intranet site of claim 40 where said paramedic site includes various interactive tools to train paramedics on patient follow up and hearing aid maintenance.
44. The intranet set of claim 40 wherein said sales/marketing site includes various interactive screens to train sales personnel in interacting with medical doctors.
45. The intranet site of claim 44 wherein said various screens provide interactive life-like interviews and sessions to enhance marketing personnel effectiveness.
46. A functional intranet system implemented in a computer to enable a user to access a selection of subsites through a terminal which is assigned an internet protocol (IP) address and provides interactive sites for user interface, the system comprising:
- the computer comprising a server and database;
  - means for connecting the terminal to the computer;
  - means for accessing the selection of subsites; and

audiovisual means associated with the selection of subsites to enable the user to hear and compare various sound levels and learn about the human ear.

47. The system of claim 46 wherein said audiovisual means includes displays associated with pre-set audiogram levels indicative of hearing profiles.

48. The system of claim 46 wherein said audiovisual means includes displays associated with pre-set audiogram levels designed to show hearing loss for patients and their families.

49. The system of claim 46 wherein said audiovisual means includes interactive graphical interfaces layerably structured to display various auditory elements of the ear.

50. A computer system for allowing a patient to access ear and acoustic information and related data using a customized interface in an intranet site, the system comprising:

- means for accessing the intranet site by the patient;
- means for displaying various interactive ear and acoustic screens; and
- means for displaying sublayers of said ear and acoustic screen.

51. The system according to claim 50 wherein said various interactive ear and acoustic screens include anatomy and physiology of the ear, physiological acoustics, psychological acoustics and speech communication screens, text and displays.

52. The system according to claim 51 wherein said anatomy and physiology of the ear include interactive screen displays of the outer, middle and inner ear.

53. The system of claim 51 wherein said physiological acoustics includes interactive screen displays of the acoustic properties of the outer and middle ear including cochlear mechanics and acoustic properties.

54. The system of claim 51 wherein said psychological acoustics includes frequency analysis and pitch perception.

55. The system of claim 51 wherein said speech communication screens includes interactive screens for acoustical analysis of speech.

56. A computer system for allowing a user to access current therapy in otology including information and related data using a customized interface in an intranet site, the system comprising:

- means for accessing the intranet site by the user;
- means for displaying various interactive otology therapy screens; and
- means for displaying sublayers of said otology therapy screens.

57. The system of claim 56 wherein said interactive otology therapy screens include external ear, middle ear and inner ear.

58. The system of claim 56 wherein an interactive resource data screen is implemented for the user to navigate relative to a given otological therapy.

59. The system of claim 56 wherein a questionnaire screen is implemented to gather information relating to the user's hearing problems.

60. The system of claim 56 wherein an interactive screen and information on a hearing aid product and its performance is implemented to instruct the user about the state of the art in otology therapy.

61. A computer readable medium having data arranged for implementing an interactive education and training intranet site in which patients, physicians, paramedics and sales personnel are trained by navigating the sites to explore the various functions of a remedial implantable medical device and the human body system, the intranet site comprising:

- a physician site;
- a patient site;
- a paramedic site; and
- a sales/marketing site.

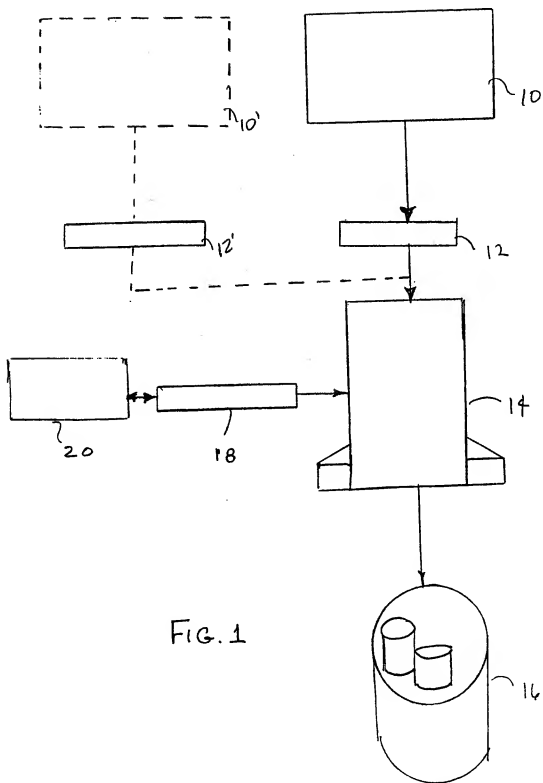


FIG. 1

FIG. 2

22

**St. Croix MEDICAL MESSAGE BOARD**

Type your user name here.  
NOTE: Do not type you "real name" in this field. Please submit the "user name" that you selected during account creation.

Name:

Type your password here.  
NOTE: Your password will not appear as you type

Password:

Clear

Home

Main Lobby

THE MAIN LOBBY

THE ENVOY SYSTEM

ST. CROIX MEDICAL

UNDERSTANDING HEARING LOSS

EDUCATION & TESTING

LIBRARY

EXIT

FIG. 3

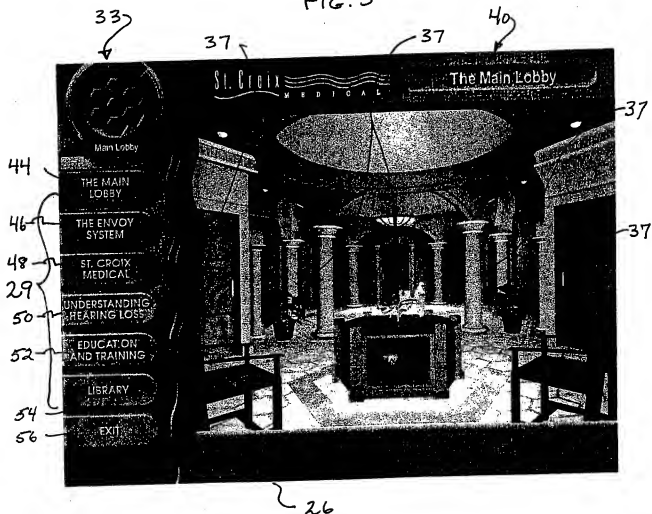
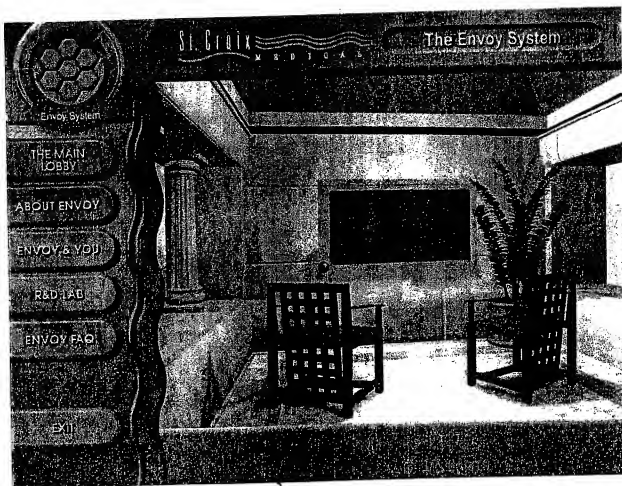


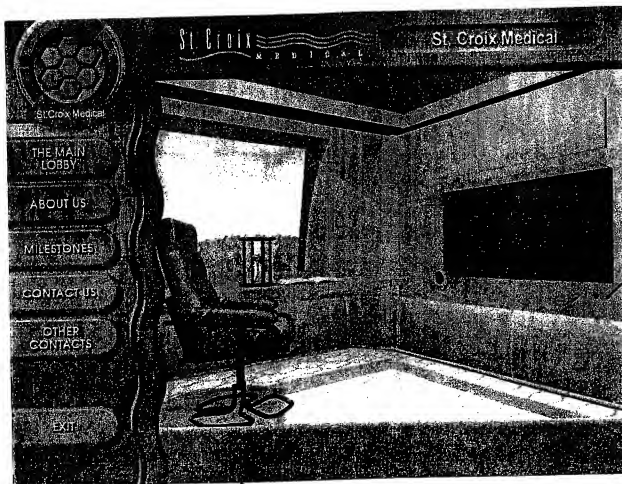


FIG. 4



65

FIG. 5



70

FIG. 6

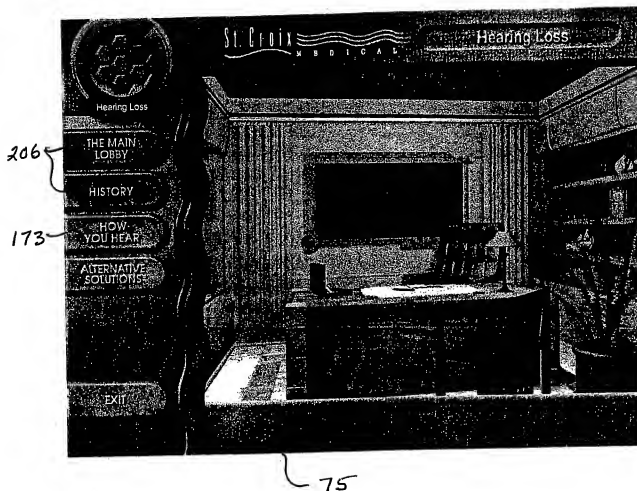


FIG. 7

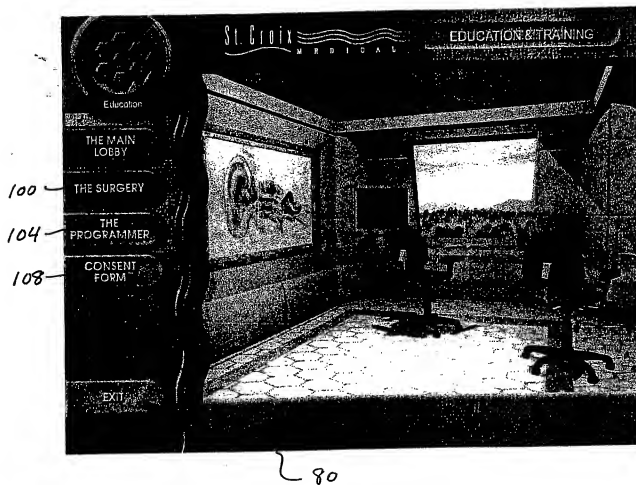
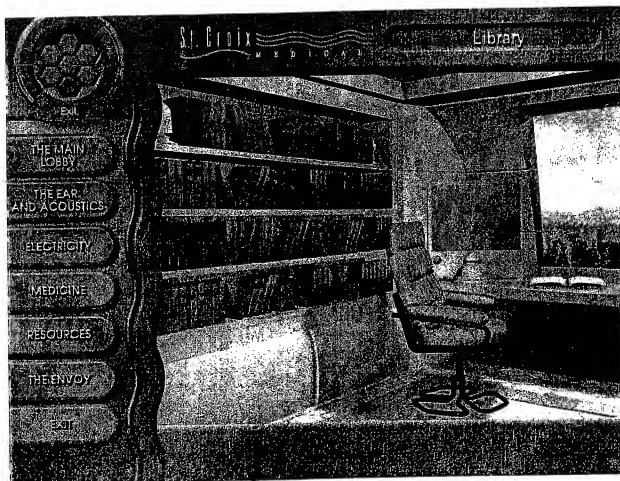


FIG. 8



85

FIG 9

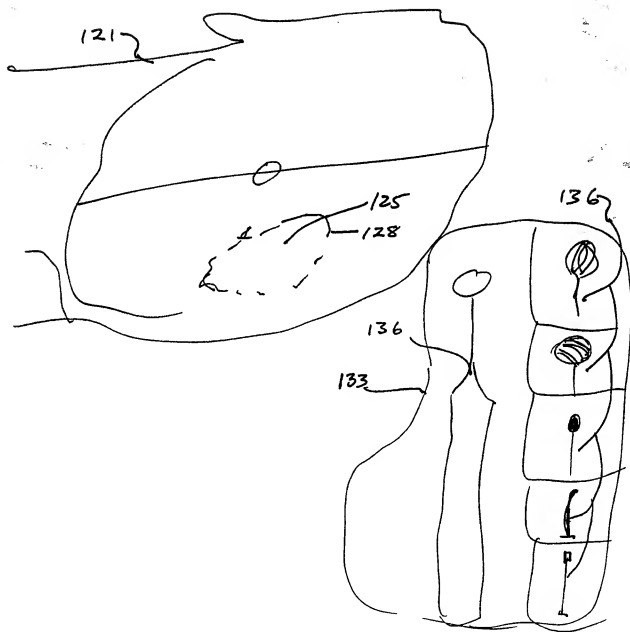


Fig. 10

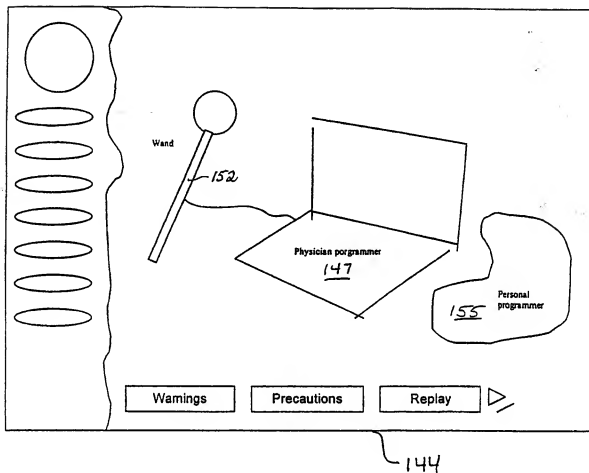


FIG. 11

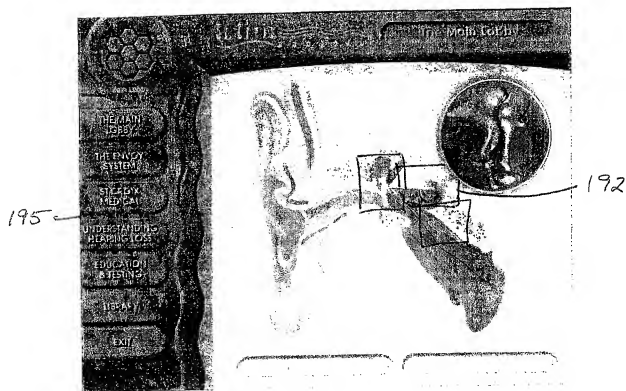
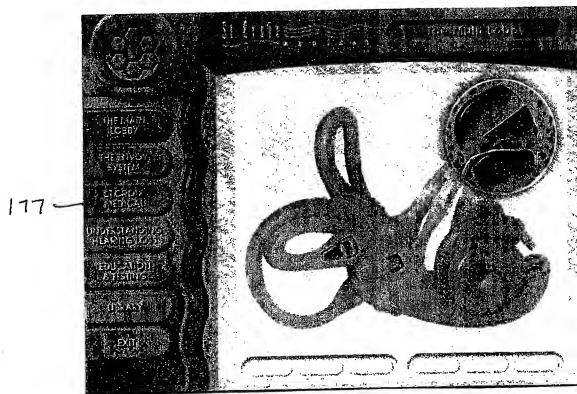


FIG. 12



201

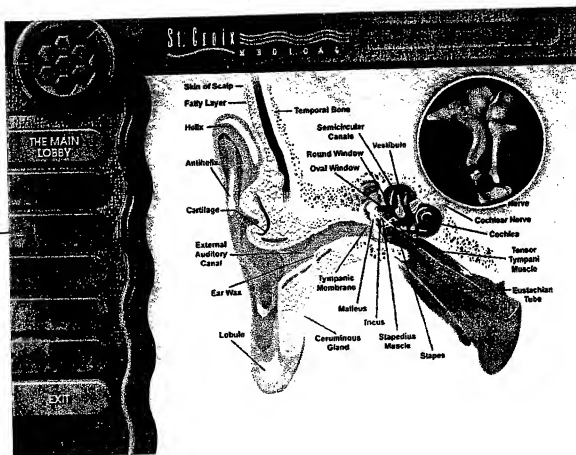
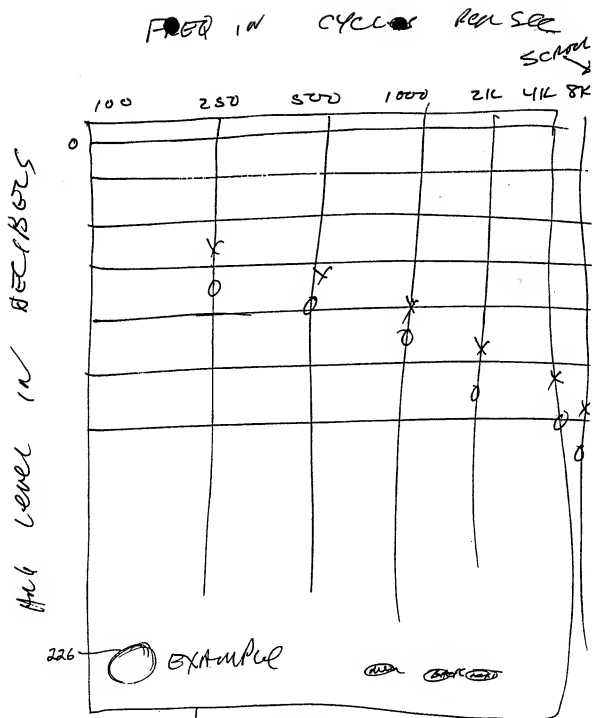


FIG. 13



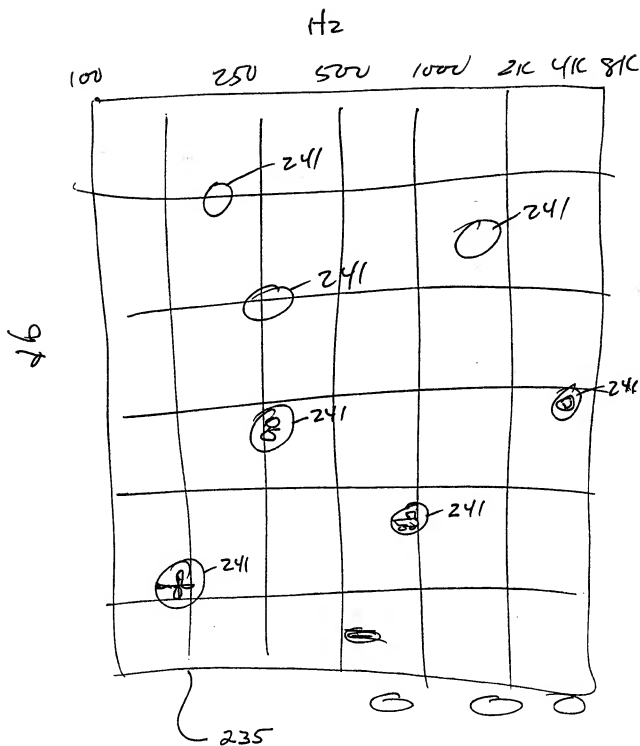


FIG 15

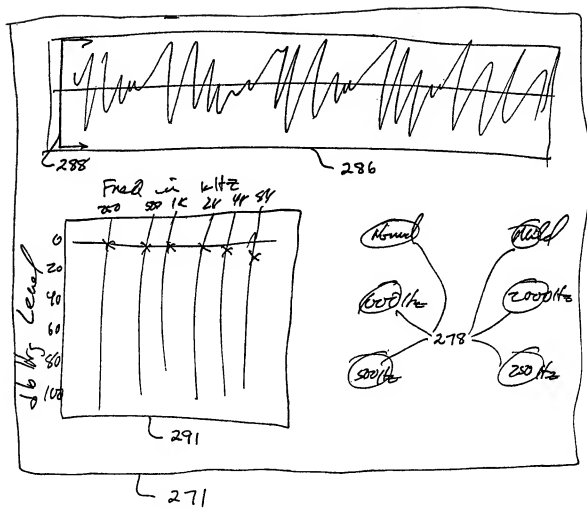


FIG. 16

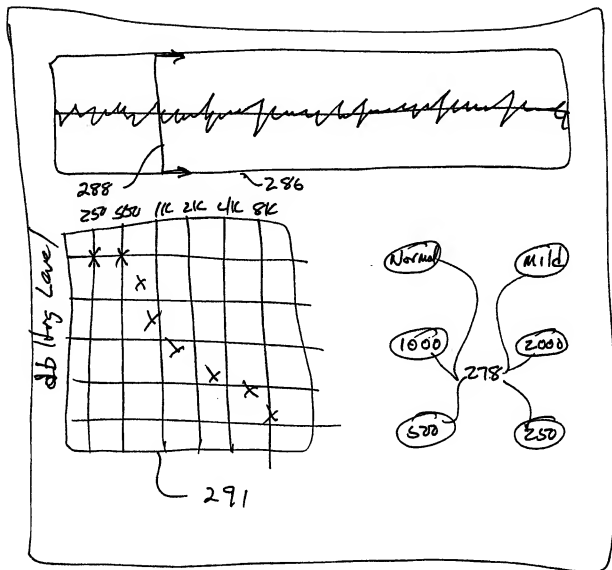


FIG. 17

FIG. 18



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/22848

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :G06F 17/60; G09B 23/28

US CL :705/2, 3; 434/267, 270

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/1, 2, 3, 7, 10; 607/57, 58, 59, 60

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Extra Sheet.

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 6,144,991 A (ENGLAND) 07 November 2000, col. 6, lines 51-58; col. 8, lines 30-34; col. 14, lines 15-28; col. 18, lines 36-43; col. 19, lines 13-35.	1-14, 16-21, 25-30, 40-61
Y	US 5,790,785 A (KLUG et al.) 04 August 1998, col. 6, lines 37-67, col. 17, lines 15-46.	1-4, 11-14, 25-30, 40-45, 50-61
Y, P	US 6,014,688 (VENKATRAMAN) 11 January 2000, col. 8, lines 32-42.	1-4, 11-14, 50-61
Y	US 5,720,771 A (SNELL) 24 February 1998, col. 2, lines 46-59; col. 6, lines 6-27.	15-30, 36-45
Y	US 4,790,019 A (HUEBER) 06 December 1988, col. 3, lines 65-68; col. 4, lines 1-17.	15-24, 36-39

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A document defining the general state of the art which is not considered to be of particular relevance	*X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*E earlier document published on or after the international filing date	*Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A document member of the same patent family
*O document referring to an oral disclosure, use, exhibition or other means	
*P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 19 DECEMBER 2000	Date of mailing of the international search report 16 JAN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer TARIQ HAFIZ <i>James R. Matthews</i> Telephone No. (703) 308-7808

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/22848

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,882,206 A (GILLIO) 16 March 1999, col. 4, lines 15-43.	16-20, 31-35
Y, P	US 6,074,213 A (HON) 13 June 2000, col. 3, lines 29-44; col. 4, lines 56-67.	15-24, 31-39
Y, P	US 5,957,699 A (PETERSON et al.) 28 September 1999, col. 1, lines 51-67; col. 2, lines 1-14; col. 3, lines 17-39.	5-10, 15-45
Y	US 4,947,432 A (T PHOLM) 07 August 1990, col. 2, lines 26-44.	15-24, 31-39
Y, P	US 6,161,139 A (WIN et al.) 12 December 2000, col. 3, lines 8-18; col. 4, lines 58-67; col. 5, lines 1-62.	5-10, 25-30, 40-49



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/22848

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**B. FIELDS SEARCHED**

Electronic data bases consulted (Name of data base and where practicable terms used):

**PROQUEST, DIALOG**

Search Terms: Envoy hearing aid, programmable, electronic forms, health care web site, self-directed learning

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING**

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-14, 46-61, drawn to a computer system and computer implemented intranet site allowing access and the submission of applications.

Group II, claim(s) 15, 21-24, 36-39, drawn to an interactively programmable system comprising a hand-held telemetry unit.

Group III, claim(s) 16-20, 31-35, drawn to a computer implemented interactive system for education and verification utilizing intranet sites.

The inventions listed as Groups I, II, and III do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I invention has utility in networked computer systems and the access and input of information thereto.

Group II invention has separate utility in telemetry hardware that interfaces with telemetry receiving units of different types.

Group III invention has utility in computer systems that interactively respond and display information based upon user input.

These inventions have acquired a separate status in the art and are shown by different classifications.